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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 10/633,194 | 07/31/2003 | Ping Gao | 01259/2/US | 3162 |
| 26648 | 7590 | 10/19/2006 | EXAMINER LAO, MARIALOUISA | |
| PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006 | | | ART UNIT 1621 | PAPER NUMBER |

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/633,194 | GAO, PING |
| | Examiner MLouisa Lao | Art Unit 1621 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 September 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 19-33 is/are rejected.
 7) Claim(s) 22-23 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/11/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Restriction

1. Applicant's election of Claims 19-33 (Group II) in the reply filed on September 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).
2. Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 27, 2006.

The requirement is still deemed proper and is therefore made FINAL.

Acknowledgement of Election of Species

3. Applicants' election of the species, i.e., sodium metabisulfite as the sulfite compound is acknowledged.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 22-23 recite the limitation "the amine agent in the capsule shell". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19, 22-24, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Satoshi et al. (EP0695544, EP '544).

The EP '544 art teaches gelatin capsules that are resistant to denaturation with the use of free radical scavengers, which are exemplified *inter alia* by pharmaceutically acceptable sulfites and hydrogen sulfites. See page 2 lines 10-17, page 3 under Example 1 and claim 4.

Further, the EP '544 art teaches that the "...generation of aldehyde is suppressed and as a result the formulation of a thin film on the gelatin capsules and insolubilization are inhibited even though PEG and the like are used as fillers." See page 3 lines 37- 43.

3. Claims 20-21, 25-29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al. (USPatent 5,733,909, USPatent '909) for the same reasons of record in a previous Office Action December 3, 2003 in response to the parent application 10/119129.

The USPatent '909 teaches a pharmaceutical composition for treating COX-2 medicated diseases comprising a particular drug of low water solubility, the selective COX-2 inhibitor having the formula (I) therein, the particular solvents such as polyethylene glycol (PEG), water and organic amine such as tertiary amine or diethanolamine. See abstract, column 1 lines 45-67; see column 10 lines 1 and 31 and column 8 lines 10-15. Further, the USPatent '909 teaches that the pharmaceutical composition therein is in the form of a capsule or an imbibable liquid to be administered orally. See column 9 line 66 to column 10 lines 1-67.

As of record in the Office Action of December 3, 2003, it had been stated that the recitation of an inherent property of a composition, e.g., "a drug of low solubility" in claim 25, would not further limit claims drawn to a composition. In the instant case, one of ordinary skill in the art would clearly recognize that the selective COX-2 inhibitor having the formula (I) therein have low water solubility since the structural formula (I) therein has indicated that the compounds therein are much less polar and not water-like.

Thus, the USPatent '909 anticipates claims 20-21, 25-29 and 33 of the instant application.

4. Claims 22, 23 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Adesunloye, et al. (USPatent 5,874,106, USPatent '106).

The USPatent '106 art teaches a filling encapsulated by a gelatin shell, wherein the filling comprises a material, which promotes crosslinking in the gelatin shell and an effective crosslinking in the gelatin shell, where the material, which promotes crosslinking in the gelatin shell, is a pharmaceutical active ingredient or a pharmaceutically acceptable excipient, or a combination thereof. See column 4 lines 27 – 57.

5. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by "Collaborative Development of Two-Tier Dissolution Testing for Gelatin Capsules and Gelatin-Coated Tablets using Enzyme-Containing Media, Stimuli to the Revision Process; *Pharmacopeial Forum*, Vol. 25, No. 5, pp 7045 –7050, Sept.-Oct. 1988 and Digenis et al.," Crosslinking of Gelatin Capsules and Its Relevance to Their In Vitro – In Vivo Performance," *J. Pharm. Sci.* 83 (7), 915-921 (1994).

Both scientific papers identified above teach dissolution test of gelatin based capsules, which is also further identified in said papers as the USP's dissolution test. See page 44 column 2 paragraph 2 of the *Pharmacopeial Forum* reference.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on 8:30am to 5:30pm Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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